

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

7561 '99 JUL 23 P4:14

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Comments:

Please see below.

Signed: *Stewart W. Wilson*

State of Residence: *Massachusetts*

As it stands, the MOU would affect one of us (Renate) directly and negatively. She uses "Estrinol", a natural estrogen source, that can only be obtained, by prescription, from a compounding pharmacist. She has had good results with Estrinol for two years, and the MOU would prevent her from getting it, since the source is outside of Massachusetts.

Renate would then be forced either to use a non-compounded (and not natural) estrogen source, or abandon the possibility of estrogen replacement therapy. Probably, she would do the latter, since the risks of non-natural --i.e., from pharmaceutical companies--sources of estrogen are substantial.

Please amend the MOU so as to ALLOW citizens and their doctors access to compounded prescriptions such as Estrinol. Since Estrinol can only be obtained by prescription, there would seem to be NO legitimate reason for the FDA to prohibit access to it!

Yours sincerely,

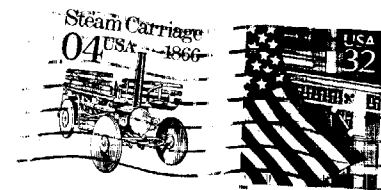
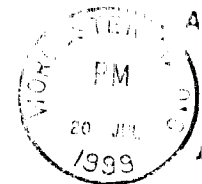
Stewart W. and Renate v. B. Wilson
30 Lang Street
Concord, MA 01742

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P.S. We have written Sens. Kennedy and Kerry, and Rep. Meehan on this.

98N-1265

S. Wilson
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